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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/812,380
Filing Date: March 29, 2004
Appellant(s): KHAN ET AL.

Ifitar Khan, Nazir Khan
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 28 May 2009 appealing from the Office action mailed 16 June 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct. However, a clarified statement of the status of the claims is as follows:

Claims 1, 3, 10, 13, and 17 have been amended subsequent to the final rejection. The Examiner believes that the amendments simplify the issues for appeal. As such, the claims as presented in the Appeal Brief filed 28 May 2009 are appealed.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect. Claims 1, 3, 10, 13, and 17 have been amended since Final rejection.

The claims presented in the Appeal Brief filed on 28 May 2009 have been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,102,884	SQUITIERI	08-2000
5,399,173	PARKS et al	03-1995
5,591,226	TREROTOLA et al	01-1997
5,509,897	TWARDOWSKI et al	04-1996

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-5, 7-10, 12-14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al.

In the specification and figures, Squitieri discloses the device substantially as claimed by applicant. With regard to claim 1, Squitieri discloses an arteriovenous shunt system comprising an arterial graft 53 with a lead end 62 anastomosed to an artery and terminal end connected to needle access site 80, which acts as a connector that corresponds to applicant's cuff. The system further comprises a venous outflow catheter 65 with an outflow end that is capable of being inserted through a vein at 40 into the right atrium of the heart (see FIGS 6-9) and an inflow end that is connected to connector 80 (see column 4). The access site 80, corresponding to applicant's cuff, directs passage of blood from the arterial catheter to the venous catheter, and is in communication with the terminal end of the arterial graft and the inlet end of the venous catheter (see FIGS 6-9, column 5, lines 19-60). Squitieri further discloses that the arterial and venous catheters may be connected in various manners by cuffs that may comprise a cylindrical shape (see FIGS 2, 4, 6, 9, 11, 12, 14).

With regard to applicant's recitation of the diameters of the arterial and venous catheters in claims 1, 4, 5, 8, 9, 12, 14, and 18, Squitieri discloses that the shunt may be manufactured in a variety of different linear lengths and interior and exterior diameter sizes (see column 3, line 60 to column 4, line 15). It has been held that where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. See MPEP § 2144.04(IV)(A). It appears that the device and method disclosed by Squitieri would perform in the same manner as claimed by

applicant. Therefore, the sizes claimed by applicant are held by the examiner to be an obvious variation of the device and method disclosed by Squitieri.

Squitieri fails to disclose that the cuff or connector comprises an inside diameter that accommodates catheters of various diameters. However, such connectors that accommodate various diameter conduits are well known in the art of fluid handling, as demonstrated by Parks. Parks discloses a medical fluid handling apparatus with a ferrule or connector 70 that receives and joins different sized conduits with graded interior wall regions 82, 84, 86 (see FIG 7, column 4, lines 55-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add a stepped or graded interior surface as disclosed by Parks to the connector between the arterial and venous catheters in the vascular access system disclosed by Squitieri in order to accommodate inserts of various diameters, as taught by Parks.

With regard to claims 2, 3, and 7, Squitieri discloses that in an embodiment, tubing or cuff 69 is made of PTFE (polytetrafluoroethylene), a biocompatible, flexible material (see FIG 8, column 5, lines 55-60).

With regard to claim 13, Squitieri discloses that the arteriovenous graft system may be connected to a hemodialysis machine (not shown), meeting the limitations of the claim (see column 4, lines 60-64).

Claims 6, 11, 15, 16, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, further in view of US 5,591,226 to Trerotola et al.

In the specification and figures, Squitieri and Parks disclose the device and method substantially as claimed by applicant (see rejection above) with the exception of the particular arteries and veins that are used to connect to the arteriovenous system. Squitieri is silent as to the particular vessels used, but it is well-known in the art of arteriovenous grafts that one may select any given vessel based on the suitability for its purpose. Trerotola discloses a stent-graft that may be deployed between many vessels within a patient, and discloses a graft between a brachial artery and an axillary vein (see FIG 9A and accompanying text). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to connect the arteriovenous graft system disclosed by Squitieri to the brachial artery and axillary vein as disclosed by Trerotola in order to create blood flow between the selected vessels, as demonstrated by Trerotola.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,591,226 to Trerotola et al.

In the specification and figures, Squitieri and Parks disclose the device and method substantially as claimed by applicant (see rejection above) with the exception of using polyurethane as a catheter material. Trerotola discloses a stent-graft that may use polyurethane as a biostable flexible material (see column 2, lines 25-33). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use polyurethane as disclosed by Trerotola in the catheter suggested by the cited prior art, since it has been held to be within the general skill of a worker in the art to

select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP § 2144.07.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,102,884 to Squitieri in view of US 5,399,173 to Parks et al, further in view of US 5,509,897 to Twardowski et al.

With regard to claim 17, the cited prior art discloses the method substantially as claimed by applicant (see rejection above). In particular, Squitieri discloses that the graft may be surgically inserted (see column 7, lines 24-45), connected to a hemodialysis machine (which, by definition, purifies blood), collect blood through the arterial catheter, send the blood through a dialysis machine, and collect blood from the dialysis machine and return it to the patient via the venous catheter (see column 4, lines 50-64). Squitieri fails to disclose that the treated blood is deposited directly into the right atrium, but suggests such an arrangement in the illustrations of FIGS 7 and 9, which show venous catheter 65 extending towards the heart via vena cava 40. Blood flows from the vena cava into the right atrium. Nonetheless, Twardowski discloses an apparatus and method for hemodialysis in which a venous catheter comprises a distal end 138a disposed within the right atrium, delivering treated blood to the right atrium in order to provide a long-term indwelling catheter (see FIG 9 and accompanying text, column 6, lines 15-48, column 11, lines 15-35). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to advance the catheter disclosed by the cited prior art deeper into the patient's vasculature to the right atrium, as disclosed by

Twardowski, in order to provide a long-term indwelling catheter without major drawbacks, as taught by Twardowski.

(10) Response to Argument

Appellant is a *pro se* Applicant, and has substantially complied with the requirements of an Appeal Brief. The Examiner is relying on the Appeal Brief filed 28 May 2009.

Appellant argues that Squitieri does not disclose an invention similar to that claimed by Appellant. Specifically, Appellant asserts that the claims of the Squitieri patent limit the length of the Squitieri catheter, making the Squitieri catheter shorter than the claimed invention. However, the Squitieri reference is relied upon for its entire disclosure. Since Squitieri discloses that the catheters may be of various sizes, the reference is reasonably relied upon to teach catheters of varied lengths that may extend into the heart, as suggested in FIG 9.

Appellant argues that the catheter disclosed by Squitieri cannot be advanced beyond the "unnamed vein" to any other position, since it is limited in length. However, as pointed out above, the Squitieri catheter is not limited to the lengths recited in the claims. A modification of the Squitieri reference does not invalidate the Squitieri patent, as alleged by Appellant, and is properly relied upon to suggest the shunt claimed by Appellant.

Appellant argues that the law requires that there be some teaching in the prior art for modification. The Examiner disagrees. In fact, there are several sources for a

motivation to combine the teachings of various references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. See *In re Rouffet*, 47 USPQ 2d 1453 (1998). In the instant case, the Squitieri reference teaches catheters of various lengths and diameters, providing sufficient motivation to modify the Squitieri teachings to arrive at Appellant's invention.

Appellant argues that the connector disclosed by Squitieri differs from the claimed cuff, since the cuff is made of biocompatible material and does not have a needle access site. The lack of a needle access site is not claimed in the instant invention. Appellant further argues structural limitations ("our venous catheter does not go through the PTFE") that are not claimed.

Appellant argues that Squitieri's invention does not set forth the diameters of the claimed catheters. Specifically, Appellant asserts that the claims of the Squitieri patent limit the diameter and the length of the Squitieri catheter, making the Squitieri catheter different than the claimed invention. However, the Squitieri reference is relied upon for its entire disclosure. Since Squitieri discloses that the catheters may be of various sizes, the reference is reasonably relied upon to teach catheters of varied diameters. Appellant further argues that since the Squitieri catheter empties into a vein rather than the heart, the mode of operation differs from the instantly claimed invention. While this may be true, there is no evidence that the diameters of the catheters affect the operation of the invention. As such, it is the position of the Examiner that Squitieri reasonably suggests catheters of various dimensions, and such a modification of the Squitieri device does not affect the performance of the Squitieri device.

Appellant further argues that the instantly claimed invention operates differently than the Squitieri device, preventing vein injury. While this may be the case, Appellant has failed to set forth what structural elements cause the instantly claimed invention to operate as claimed. Absent patentably structural differences between the instantly claimed invention and the suggestion of the prior art, the mode of operation does not patentably distinguish device claims.

Appellant argues that the Parks apparatus is non-analagous art since Parks teaches a gastronomy tube. The Examiner respectfully disagrees. It has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See In re Oetiker, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, the Examiner relies on the Parks reference to teach a connector that connects two fluid conduits, which is analogous to both the concept of fluid transfer in Squitieri and Appellant's invention. One of ordinary skill in the art would be motivated to look to connectors in fluid transfer devices to provide a connector for the fluid transfer device disclosed by Appellant. Appellant further argues that the connector disclosed by Park must be placed within the arterial catheter of the Squitieri invention and that the ridged inner surface of Park would disrupt blood flow therethrough. The Examiner notes that Park discloses that interior wall regions 82, 84, and 86 accommodate different sized connections. Such a disclosure indicates that catheters may be placed within the Parks connector, creating a smooth surface for blood flow through the connector. As such, the combination of

Squitieri and Parks does not necessarily destroy the function of the primary reference nor the claimed invention.

Appellant argues that Squitieri does not retain authority over all hemodialysis devices. The Examiner is relying on Squitieri to teach the general concept of a hemodialysis shunt that is similar to that claimed by Appellant.

Appellant argues that the names of the particular arteries and veins must be mentioned in order to construct an arteriovenous shunt. The Examiner respectfully disagrees, and notes that it is well-known in the art to place catheters in various vessels, as demonstrated by the cited references. Appellant argues that using the shunt disclosed by Trerotola cannot be used for dialysis, since it will damage the vessel. However, the Examiner is relying on Trerotola to teach only that it is known to place catheters in the claimed locations, and that one having ordinary skill in the art would place the catheter as suggested by Squitieri and Parks in the locations taught by Trerotola.

Appellant argues that the rejection of claim 10 should be withdrawn. However, the Examiner notes that polyurethane is a biocompatible material, meeting the limitations of the claims.

In response to applicant's argument that the Squitieri and Twardowski devices are not combinable, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would

have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, the cited prior art suggests placement of a catheter in the right atrium to return treated blood to the patient, meeting the limitations of the claims.

Appellant argues that the instantly claimed vascular access device provides an improvement over the prior art. While Appellant's evidence in support of the claimed improvements tend to show improved patency and reduced infection rate, the evidence fails to show that the results were truly unexpected. Appellant further alleges that the instantly claimed invention solves a long-felt need in the art, but provides no evidence of this need, unsuccessful attempts by others, nor evidence that the instantly claimed invention actually solves the need. As such, Appellant's arguments with regard to secondary considerations fail to overcome the rejections over the prior art.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Leslie R. Deak/

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